REMARKS

Claims 1, 6-37 and 43-46 are pending in the present application. Claims 2-5 and 38-42 have been canceled previously. Claim 29 is amended to recast into independent form and more closely correspond to the count proposed for an interference. Claim 30 was amended to be dependent on claim 29. Neither amendment contains new matter nor was the amendment made to narrow the claim for the purpose of patentability.

Applicants thank Examiner George for the telephone interview on November 21, 2003. During that conversation Examiner George concurred with Applicants that the cited reference was not an prior art prior art reference for the reasons discussed below.

Claims 1, 6-37 and 43-46 are rejected under 35 U.S.C. §103(a) as unpatentable over Tong *et al.* (U.S. 6,515,022 B2).

Applicants respectfully traverse the rejection under 35 U.S.C. §103(a). The cited Tong patent (U.S. Pat. No. 6,515,022, hereafter the '022 patent) is not an appropriate prior art reference against the present application.

The present application, U.S. 20020049252, (U.S. Ser. No. 09/966,202, the '202 application) is a divisional application of U.S. Ser. No 09/631,151, now U.S. Patent No. 6,339,107, (hereafter the '107 patent) which was filed **August 2, 2000**. The '202 application claims benefit of the August 2 2000 priority date. The subject matter in the current case also is closely related to the parent application; however, the dose ranges are larger than those recited in the parent.

The '022 patent was filed on **May 11, 2001**. The '022 patent is a continuation-in-part of US 6,251,941 (hereafter the '941 patent) which has a §371 date of December 29, 1998, admittedly prior to the filing date of either the Belloni '107 patent or the current application. The '941 patent provides a method to administer highly water-insoluble retinoic acids to the respiratory tract as ammonium salts to treat a cancer of the respiratory tract, not emphysema or fibrotic lung disease. No reference to emphysema or the treatment of emphysema is found in the '941 Tong patent. The claims to treatment of emphysema in the '022 continuation-in-part are new matter and the cited reference, therefore, is not entitled to the benefit of priority to the filing date of the '941 patent for claims to treatment of emphysema.

Since the priority date of the present application is earlier than the priority date of the Tong patent it is not prior art to the present application.

Withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

APPLICANTS NOW COMPLY WITH CFR 37 §1.604:

(a) An applicant may seek to have an interference declared with an application of another by,
  (1) Suggesting a proposed count and presenting at least one claim corresponding to the proposed count or identifying at least one claim in its application that corresponds to the proposed count,
  (2) Identifying the other application and, if known, a claim in the other application which corresponds to the proposed count, and
  (3) Explaining why an interference should be declared.

(b) When an applicant presents a claim known to the applicant to define the same patentable invention claimed in a pending application of another, the applicant shall identify that pending application, unless the claim is presented in response to a suggestion by the examiner. The examiner shall notify the Commissioner of any instance where it appears an applicant may have failed (CFR 37 §1.604)

I. THE PROPOSED COUNT
Pursuant to 37 CFR §1.607(a)(1) the following single count is proposed:

1. A method for the treatment of emphysema in an individual, comprising administering by inhalation to the respiratory tract of the individual an air-borne composition comprising a therapeutically effective amount of 13-*cis*-retinoic acid or an amine salt thereof.

II. TONG'S CLAIMS CORRESPONDING TO THE COUNT

Claims 1-4, 6-7, 9, 16-18 and 20-21 of the '022 patent recite administering a composition comprising ... at least one retinoid". Claim 5 which is dependent on claim 1 contains the limitation that the retinoid is all-*trans* retinoic acid. "Under the doctrine of claim differentiation, 'each claim in a patent is presumed different in scope.' This presumption is especially strong where 'there is a dispute over whether a dependent claim should be read into an independent claim and the limitation is the only meaningful difference between the two claims" (*Ecolab Inc. v. Paraclipse, Inc.* 6 USPQ2d 1349 (Fed. Cir. 2002); references omitted). The '022 patent further depicts the structures of clinically significant retinoids in FIG 1 (col. 1, lines 59-60). 13-*cis*-Retinoic Acid is shown in FIG 1. "Retinoids of particular interest in the present invention are all-*trans*-retinoic acid, 13-*cis*-retinoic acid and 9-*cis*-retinoic acid, and salts and esters thereof." (col.

3, lines 29-31). The implication is clear: the inventor contemplates using any one of the natural retinoids including 13-*cis*-retinoic acid.

Claims 1-4 and 6-7 of the '022 patent recite a method for the treatment of lung disease comprising administering compositions comprising at least one retinoid. Claims 2-4 and 6-7 dependent on claim 1 recite compositions containing an amine and a retinoid. Claim 9 and 16-18 and 20-21 recite method for the treatment of emphysema comprising administering compositions comprising at least one retinoid. Applicants suggest that claims 1-4, 6-7, 9, 16-18 and 20-21 all read on the proposed count.

Claims 8, 10-12 and 14-15 recite a method of the treatment of fibrotic lung disease comprising administering compositions comprising at least one retinoid. Claims 5, 13 and 19 recite treatment of lung disease, fibrotic lung disease and emphysema with all *trans* retinoic acid. Applicants suggest that claims 5, 8, 10-15 and 19 do not read on the proposed count.

It as further submitted that if the 850 Form is completed, Tong should not be accorded the benefit of the priority date of the earlier US 6,251,942.

III. APPLICANTS' CLAIMS CORRESPONDING TO THE COUNT

Claim 29 of the present application is amended in the present paper

> 29. The method for treating emphysema and related disorders comprising delivering a formulation of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, into the lungs of the mammal with an aerosol device.

Prior to the amendment of claim 29 into independent form, claim 24 and dependent claim 29 read:

> 24. A method for treating emphysema and related disorders comprising delivering a formulation of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, into the lungs of a mammal.

29. The method of Claim 24, wherein the formulation is delivered into the lungs of the mammal with an aerosol device.

The amendment simply recasts claim 29 into independent form and does not constitute new matter. Furthermore restating claim 29 independent does not represent a narrowing amendment made for the purposes of patentability. Claim 29 recites a method wherein 13-*cis*-retinoic acid is administered into the lungs of a mammal with an aerosol device. An aerosol is defined as "a suspension of fine solid or liquid particles is gas." (Websters New Collegiate Dictionary 1979, p.19). An aerosol therefore corresponds to an airborne composition and the lungs are a portion of the respiratory tract afflicted with emphysema. Claim 29 includes salts of 13-*cis*-retinoic acid. The specification defines "pharmaceutically acceptable salts" to include organic and inorganic bases. The specific examples or organic bases include primary, secondary and tertiary amines (p. 5, lines 30-33). Claim 29 reads on the proposed count.

Claim 1 of the present invention and claims 6-10 and 21-22 which depend therefrom also correspond to the proposed count. Claim 1 recites a method for the treatment of emphysema with 13-*cis*-retinoic acid without any limitation on the formulation or application method. The specification teaches delivery of 13-*cis*-retinoic acid by a variety of routes including inhalation (p. 13, line 10 to p. 14, line 29). Examples 1-5 recite formulations for delivery *via* oral and inhalation routes.

The proposed count also corresponds to claim 24 of the present invention and claims 25-28 which depend therefrom. Claim 24 recites a method for the treatment of emphysema by delivering 13-*cis*-retinoic acid into the lungs of a mammal.

The proposed count does not correspond to claim 31 of the present invention and claim 32 which depends therefrom. Claim 31 recites a method for the treatment of emphysema with 13-*cis*-retinoic acid in combination with other therapies.

The proposed count does not correspond to claim 33 of the present invention and claim 35 which depends therefrom. Claim 31 recites a method for the preventing of emphysema with 13-*cis*-retinoic acid.

The proposed count does not correspond to claim 11 and claims 12-20 which depend therefrom or claim 35 and claims 36, 37 and 43-45 which depend therefrom. Claims 11-20, 35, 36-37 and 43-45 are pharmaceutical composition claims.

> Although a patent which has an effective U.S. filing date later than the effective filing date of an application is not prior art against the application, the application should not be issued if the application and patent contain claims to the same patentable invention. In order to avoid issuance of two patents to the same patentable invention the Examiner should take steps to initiate an interference between the application and patent. (MPEP §2306.01)

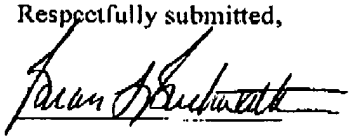
Both the present application and the cited reference claim the same invention. The Examiner is requested to provoke an interference.

CONCLUSIONS

The present application has a filing date prior to the cited and reference and withdrawal of the rejection is requested. To avoid issuance of a second patent to the same patentable invention the Examiner is respectfully requested to declare an interference between the present application and US 6,251,941.

The amendment recasting dependent claim 29 into independent form does not requirement an additional fee since previously payment was made for five independent claims one of which was subsequently canceled. Therefore, additional fees should be due with this application; however if any fee is required the Examiner is authorized to charge the fee to Deposit Account 18-1700.

Respectfully submitted,



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